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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,047	09/23/2002	Manuel Fresno Escudero	34909-PCT USA 069277.0108	8670
21003	7590	05/19/2004	EXAMINER PAK, YONG D	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/031,047	ESCUDERO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 30 March 2004.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 10-25 is/are pending in the application.
  - 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/5/02</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

The amendment filed on January 10, 2001, canceling claims 1-9 and adding claims 9-24, has been entered. The amendment filed on September 17, 2003, renumbering claims 9-24 to claims 10-25, has been entered.

Claims 10-25 are pending.

#### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 10-24 ) is acknowledged.

Claim 25 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on May 27, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. Claims 14-15 read on a product of nature. This rejection can be overcome by amending claims 14-15 as "an isolated peptide", for example.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 12-14 and 16-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10 and 12-13 and 18-22 are drawn to a human cyclooxygenase 2 gene having any structure. Claims 14 and 16-17 are drawn to a 1.9 kb human cyclooxygenase 2 promoter having any structure. Therefore, these claims are drawn to a genus of polynucleotides having undefined structure. Art teaches that there are more than one human cyclooxygenase 2 (form PTO-892 – Proc. Natl. Acad. Sci. USA, Vol.

93, pp. 4816-4820, May 1996). The specification only teach the promoter of the human cyclooxygenase 2 gene of SEQ ID NO:5. The specification fails to describe any other cyclooxygenase 2 genes by any identifying characteristics or properties other than being about 1.9 kb or having a sequence from about nucleotide -1796 to about +104.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 10, 12-14 and 16-22.

Claim 10, 12-14 and 16-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid molecule of SEQ ID NO:5, does not reasonably provide enablement for a human cyclooxygenase 2 gene of undefined structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to polynucleotides having undefined structure. As stated previously, art teaches that there are more than one human cyclooxygenase 2 (form PTO-892 – Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 4816-4820, May 1996). The specification only teaches the human cyclooxygenase 2 gene of SEQ ID NO:5. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The quantity of experimentation in this area is extremely large since there is significant variability in the structure of the polypeptides. It would require many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its structure. Due to the insufficient teaching of the structure, it is entirely unpredictable what structure will be found for the broadly encompassed polypeptides.

Therefore, one of ordinary skill would require guidance in order to use polynucleotides encoding polypeptides having unknown function in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the microorganism(s) (ECACC 9903245 and CECT 5145) is/are required to practice the claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it/they is/are not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the microorganism(s). See 37 C.F.R. § 1.802.

The specification does not provide a repeatable process for obtaining the microorganism(s) and it is not apparent if the microorganism(s) is/are readily available to the public. The specification must contain the date that the microorganism(s) was/were deposited, the name of the microorganism(s) and the address of where the microorganism(s) was/were deposited.

If the deposit(s) has/have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

If the deposit(s) has/have not been made under the Budapest Treaty, then in order to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request; (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent; (c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; (d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807; and (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. § 1.809 (d) should be added to the specification. See 37 C.F.R. § 1.803-1.809 for additional explanation of these requirements.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 12-14 and 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 10, 12-14 and 16-24, without the recitation of the SEQ ID NO, the structure of the nucleic acid sequence is unclear.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-24 are rejected under 35 U.S.C. 102(b) as being anticipated by

Kutchera et al.

Kutchera et al. (form PTO-892 – Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 4816-4820, May 1996) teach a nucleic acid molecule comprising a nucleic acid molecule encoding a human cyclooxygenase type 2 that is 100% identical to SEQ ID NO:5 of the instant invention (abstract, pages 4817-4818). The nucleic acid molecule of Kutchera et al. is linked to a luciferase gene. Kutchera et al. also teach a nucleic acid molecule comprising about 1.9 kb of a human cyclooxygenase 2 promoter linked to a luciferase gene (pages 4817-4818). Kutchera et al. also teach a cell comprising said nucleic acid molecules (pages 4817-4818). Therefore, the teachings of Kutchera et al. anticipate claims 10-24.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak  
Patent Examiner



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